



PTO/SB/08a (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE aperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

	Application Number		10593261				
	Filing Date		2007-07-11				
	First Named Inventor	Lars N	Michael Larsen				
	Art Unit		1614				
	Examiner Name						
	Attorney Docket Number		LARSEN=5				

	U.S.PATENTS									
Examiner Initial*	r Cite No Patent Number		Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear				
	1	5552369		1996-09-03	FINDEISEN et al.					
	2	5624949		1997-04-29	William E. HEATH Jr. et al.					
	3	5674862		1997-10-07	William E. HEATH Jr. et al.					
<i>;</i>	4	5698578		1997-12-16	William E. HEATH Jr. et al.					
	5	5710145		1998-01-20	Gaey Lowell ENGEL et al.					
	6	5824685		1998-10-20	Peter A. CAMPOCHIARO et al.	:				
	7	6015807		2000-01-18	Gaey Lowell ENGEL et al.	•				
	8	6114320		2000-09-05	Lloyd P. AIELLO et al.	· · · · · · · · · · · · · · · · · · ·				

If you wish to add additional U.S. Patent citation information please click the Add button.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	10593261
Filing Date	2007-07-11
First Named Inventor	Lars Michael Larsen
Art Unit	1614
Examiner Name	
Attorney Docket Numb	DOT LARSEN=5

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Ation Number Kind Code ¹ Publication Name of Patentee or Applie of cited Document		of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20030032078	A1	2003-02-13	Gabriel H. TRAVIS	

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

	TORLION FATER BOOGINERTO								
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² j	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T5	
	1	2005107707	wo	A1	2005-11-17	Allergan, Inc.			
	2	02080936	wo	A1	2002-10-17	Ortho McNeil Pharmaceutical, Inc.			
	3	2005058304	wo	A1	2005-06-30	Cortical Pty Ltd.			
	4	03104178	wo	A1	2003-12-18	Cortical Pty Ltd.	9.9		
	5	02080935	wo	A1	2002-10-17	Ortho McNeil Pharmaceutical, Inc.			
	6	03097052	wo	A2	2003-11-27	Celgene Corporation			
	7	99058126	wo	A1	1999-11-18	The Endowment for Research in Human Biology, Inc.			

NFORMATION DISCLOSURE			7.55				10593261			
							2007-07-11			
				First Named Inventor Lars M				Michael Larsen	Vichael Larsen	
STATEMENT BY APPLICANT Not for submission under 37 CFR 1.99)				Art Unit				1614		
NOLIOF	ission under 37 CFR	Exami	iner Na	me						
			Attorn	ey Doc	ket Numb	er	LARSEN=5			
_				1				.,		
						T		·		Т
	8	02072003	wo		A2	2002-09-1	9	Tomas HAGSTROM		
	9	02085400	wo		A1	2002-10-3	:1	Supergen, Inc.		
	10	0198294	wo		A2	2001-12-2		Dupont Pharmaceuticals Company		
	11	03004058	wo		A1	2003-01-1	^	Santen Pharmaceutical Co.	Abstract	×
	12	2005056010	wo	•	A1	2005-06-2	:3	Allergan, Inc.		
	13	2005011741	wo		A2	2005-02-1	0	Allergan, Inc.		
	14	03082081	wo		A2	2003-10-0	19 I	Maxim Pharmaceuticals, Inc.		
	15	0522226	EP		A1	1993-01-1	3	Ciro COSTAGLIOLA		
f you wisl	h to a	dd additional Foreign P	atent Do	cument	citation	informatio	n ple	ase click the Add buttor	1	
			NON	-PATEN	NT LITE	RATURE	DOC	UMENTS		
Examiner nitials*	Cite No		nal, seria	i, symp	osium,	catalog, et		ne article (when appropr ate, pages(s), volume-is		T5
1		PAUL A. SIEVING et al. "Inhibition of the visual cycle in vivo by 13-cis retinoic acid protects from light damage and provides a mechanism for night blindness in isotretinoin therapy", Proc. Nat. Acad. Sci. (USA), February 13, 2001, Vol. 98 No. 4, pages 1835-1840								

Application Number 10593261 2007-07-11 Filing Date INFORMATION DISCLOSURE First Named Inventor Lars Michael Larsen STATEMENT BY APPLICANT Art Unit 1614 (Not for submission under 37 CFR 1.99) **Examiner Name** LARSEN=5 Attorney Docket Number ROXANA A. RADU et al., "Treatment with isotretinoin inhibits lipofuscin accumilation in a mouse model of recessive 2 Stargardt's macular degeneration", Proc. Nat. Acad. Sci. (USA), April 15, 2003, Vol. 100, No. 8, pages 4742-4747 JANET R. SPARROW, "Therapy for macular degeneration: Insights from acne", PNAS, April 15, 2003, Vol. 100, No. 8, 3 pages 4353-4354 G. B. ARDEN, "The absence of diabetic retinopathy in patients with retinitis pigmentosa: implications for 4 pathophysiology and possible", Br F Ophthalmol, 2001, Vol 85, pages 366-370 LERMAN, S., "Ocular side effects of accutane therapy", Lens and Eye Toxicity Research, 1992, Vol. 9(3-4), pages 5 429-38. DEVIPRASAD R. GOLLAPALLI et al., "Specifc inactivation of isomerohydrolase activity by 11-cis-retinoids", Science 6 Direct, Biochimica et Biophysica Acta 1651 (2003) pages 93-101 DEVIPRASAD R. GOLLAPALLI et al., "All-trans-retinyl Esters Are the Substrates for Isomerization in the Vertebrate 7 Visual Cycle", Biochemistry, April 25, 2003, Vol. 42 pages 5809-5818 DEVIPRASAD R. GOLLAPALLI et al., "RPE65 Operates in the Vertebrate Visual Cycle by Stereospecifically Binding 8 All-trans-Retinyl Esters", Biochemistry, September 17, 2003, Vol. 42, pages 11824-11830 PAUL S. BERNSTEIN et al., "Mechanism of Action of Aromatic Amines That Short-Circuit the Visual Cycle", 9 Biochemistry, 1986, Vol. 25, pages 3370-3377 N DRASDO et al., "Effect of darkness on inner retinal hypoxia in diabetes" The Lancet, Vol. 359, June 29, 2002, pages 10 2251-2253 ANETTE WINSTON et al., "Regulation of Isomerohydrolase Activity in the Visual Cycle", Biochemistry, February 3, 11 1998, Vol. 37, pages 2044-2050 G.B. ARDEN et al., "Does dark adaptation exacerbate diabetic retinopathy? Evidence and a linking hypothesis", 12 Vision Research, Vol. 38, 1998, pages 1723-1729

Application Number 10593261 Filing Date 2007-07-11 INFORMATION DISCLOSURE First Named Inventor Lars Michael Larsen STATEMENT BY APPLICANT Art Unit 1614 (Not for submission under 37 CFR 1.99) **Examiner Name** Attorney Docket Number LARSEN=5 ANNA WROBEL et al., "Antiangiogenic activity of agonist and antagonists of retinoid nuclear receptors", Przeglad $|\mathbf{x}|$ 13 Dermatologiczny, 1999, Vol. 86, No. 4, pages 339-346 (in Polish) MICHAEL F. MARMOR, et al., "Albipunctate Retinopathy with cone Dysfunction and no Abnormality in the RDH5 or 14 RLBPI Genes", Retina 2003 United States, Vol. 23, Vol. 4, pages 543-546 B. M. CALISSENDORFF, "Retinal changes degeneration or side effects caused by etretinate therapy Tigason" Klin. 15 X Mbl. Augenheilk, Vol. 194, 1989, pages 187-189 (in German) TSUTOMU OIKAWA et al., "Three novel synthetic retinoids, Re 80, Am 580 and Am 80, all exhibit anti-angiogenic 16 activity in vivo", Europ J. of Pharmac., Vol. 249, 1993, pages 113-116 SELIG HECHT et al., "Rod-Cone Dark Adaptation and Vitamin A", Science, New Series, Vol. 88, No. 2279, September 17 2, 1938, pages 219-221 JOHN E. DOWLING et al., "Vitamin a Deficiency and Night Blindness", Proc. Natl. Acad. Sci. USA Vol. 44, (1958) 18 pages 648-661 RICHARD G. WELEBER et al., "Abnormal Retinal Function Associated with Isotretinoin Therapy for Acne", Arch 19 Opthalmol, Vol. 104, June 1986, pages 831-837 H. MACLEAN et al., "Abnormal night vision with isotretinoin therapy for acne", Clinical and Experimental Dermatol, Vol. 20 20, page 86, January 1995, 21 ROSALIE K. CROUCH et al., "Retinoids and the Visual Process", Photochem. Photobiol., Vol. 64, pages 613-621 F. T. FRAUNFELDER, et al., "Ocular Side Effects Possibly Associated with Isotretinoin Usage", Am. J. Opthalmol, Vol. 22 132, 2001, pages 299-305

WING C. LAW et al., "The Molecular Basis of Retinoic Acid Induced Night Blindness"Biochem. Biophy. Res. Comm.,

23

Vol. 161, No. 2, pages 825-829

Application Number 10593261 2007-07-11 Filing Date INFORMATION DISCLOSURE First Named Inventor Lars Michael Larsen STATEMENT BY APPLICANT 1614 Art Unit (Not for submission under 37 CFR 1.99) **Examiner Name** LARSEN=5 Attorney Docket Number BELINDA M. WELSH et al., "Night blindness precipitated by isotretinoin in the setting of hypovitaminosis A", Australas 24 J Dermatol, Vol. 40, 1999, pages 208-210 G. P. MOSS et al., "Nomenclature of Retinoids", Arch. Biochem., Biophys. Vol. 224, No. 2, July 15, 1983, pages 25 728-731 BRAHMA P. SANI et al., "Structural Characteristics of Synthetic Retinoids", Meth. In Enzymology, Vol. 189, 1990, 26 pages 43-59 MICHAEL KLAUS, "Structure Characteristics of Natural and Synthetic Retinoids" Meth. In Enzymology, Vol. 189, 27 (1990) pages 3-14 M. I. DAWSON et al., "Synthetic Retinoic Acid Analogs: Handling and Characterization", Meth. In Enzymology, Vol. 28 189. . 1990. pages 15-43 GREGORY M. ACLAND et al., "Gene therapy restores vision in a canine model of childhood blindness", Nature 29 genetics, Vol. 28, May 2001, pages 92-95 T. MICHAEL REDMOND et al., "Rpe65 is necessary for production of 11-cis-vitamin A in the retinal visual cycle", 30 Nature Genetics, Vol. 20, December 1998, pages 344-351 PAUL S. BERNSTEIN et al., "The Specific Inhibition of 11-cis-Retinyl Palmitate Formation in the Frog Eye by 31 Diaminophenoxypentane, An inhibitor of Rhodopsin Regeneration", Vision Res., Vol. 25, No. 6, 1985, pages 741-748 32 BROWN, et al., "Visual toxicity of synthetic retinoids", British Journal of Ophthalmology, Vol. 73, pages 286-288, 1989. CAFFERY, et al., "Ocular side effects of isotretinoin therapy", Journal of the American Optometric Association, Vol. 59, 33 No. 3, pages 221-224, March 1988. DENMAN, et al., Abnormal night vision and altered dark adaptometry in patients treated with isotretinoin for acne", 34 Journal of the American Academy of Dermatology, Vol. 14, No. 4, pages 692-693, April 1986.

•										
		Application Number		10593261						
				Filing Date		2007-07-11				
	INFORMATION DISCLOSURE			First Named Inventor	Lars	Michael Larsen				
			BY APPLICANT	Art Unit		1614				
(NOT TOP	Subii	1155101	under 37 CFR 1.99)	Examiner Name						
				Attorney Docket Numb	er	LARSEN=5				
	35	FEIST, et al., "Visual Side Effects of Isotretinoin Therapy", SOUTHERN MEDICAL JOURNAL, Vol. 80, No. 10, page 1332, October 1987.								
	36		JNFELDER, et al., "Adverse nalmology, Vol. 100, pages s	Ocular Reactions Possibly Associated with Isotretinoin", American Journal of 534-537, October 1985.						
	37	GRO	SS, et al., "Retinoids and the	e Eye", Dermatologic Clinics	, Vol. 1	I0, No. 3, pages 521-531, July 1992.	С			
If you wis	h to a	dd add	litional non-patent literatu	re document citation info	rmatio	n please click the Add button		_		
				EXAMINER SIGNA	TURE			_		
Examiner Signature						Date Considered				
						rmance with MPEP 609. Draw line the ith next communication to applicant.	rough a			
Standard St	T.3). 3	For Japa	anese patent documents, the inc	dication of the year of the reign	of the E	office that issued the document, by the two-lett imperor must precede the serial number of the ard ST.16 if possible. ⁵ Applicant is to place a	patent docume	ent.		

English language translation is attached.